ST. JOHN'S
PHYSICIANS & CLINICS

Orthopedic Association

David W. Brown, M.D.
James T. Shaeffer, M.D.
Clyde W. Parsons III, M.D.
Fred G. McQueary, M.D.
Michael P. Nachtigal, M.D.
Paul M. Olive, M.D.
Thomas D. McClain, M.D.
R. Bradley Wyrsch, M.D.

December 1, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 97N-484S

Dear Sirs:

I am writing to respond to the proposed regulation that appeared in the September 30, 1999 issue of the Federal Register. I strongly do not feel that the FDA should be regulating allograft materiai as a "medical device". This is certainly not within the realm of implants for which this particular legislation is designed.

I currently use machined allograft bone dowels for interbody fusions and have had excellent results doing so. As you are aware, non-machined implants have been used without regulation for years, and have an excellent track record. The simple fact that machining this allograft material to better fit the patient, does not alter the fact that this material utilizes is actual bone and not an artificial "device". Altering this regulation to allow FDA oversight on this process, could very likely remove from the market place machined allograft bone material which has already been demonstrated to be a good improvement over the previously used fusion material.

I strongly feel this regulation should not be adopted as written.

Sincerely,

Fred G. McQueary, M.D.

FGM:jh

97N-484S

C25

2115 South Fremont, Suite 1000 • Springfield, Missouri 65804 • 417-882-6040 or 1-800-383-4063

ST. JOHN'S
PHYSICIANS & CLINICS
A member of the Sisters of Mercy Health System–St. Louis

Orthopedic Association

2115 S. Fremont, Suite 1000 • Springfield, MO 65804-2208

RETURN SERVICE REQUESTED

PRESORTED FIRST CLASS

SPRINGFIELD MO DEC 03'99

PB METER 7024913 $ 00.30 U.S. POSTAGE

Document Mgmt. Branch (HFA 305)
Food + Drug Adm.
5630 Fishers Lane Room 1061
Rockville Md 20852

Docket 99N 4845 MOTO 00057